PATIENT INFORMATION LEAFLET

Urever 20 mg/2 mL I.M./I.V. Ampoule Containing Solution
Sterile
For intramuscular/intravenous use

- ***Active substance:*** Each ampoule contains 20 mg furosemide.
- ***Excipients:*** Sodium hydroxide, sodium chloride and water for injection.

Read all of this leaflet carefully before starting to use this medicine; because important information is included here.

- *Keep this leaflet. You may need to read it again.*
- *If you have any further questions, please consult your doctor or pharmacist.*
- *This medicine has been prescribed for you personally, and you should not pass it on to*
- *others.*
- *During the use of this medicine, please tell your doctor that you are using this drug when you visit your doctor or a hospital.*
- *Follow exactly what is written in this instruction. Do not use dosages* ***higher or lower*** *than the dosage recommended to you.*

In This Leaflet:

Titles include.

1. What is UREVER and what it is used for?

UREVER is in the form of a 2 mL ampoule containing 20 mg of furosemide active substance, administered intramuscularly or intravenously. It is available in packages containing 5 or 100 ampoules.

UREVER is included in a group of drugs called diuretics. Diuretics are drugs that increase the rate of urine excretion from the kidneys and also cause water and salt loss. It is used for help to reduce the amount of the excess fluid and it may also be used to lower high blood pressure. UREVER is an effective diuretic.

Your doctor may have prescribed UREVER for one or more of the following reasons:

• Respiratory failure due to ongoing heart failure, edema, excessive fluid retention in the body to the inability to expel excess fluid because of liver enlargement.
• Excessive fluid retention in the body due to the inability to expel excess fluid associated with ongoing kidney failure.
• Continuing fluid excretion in acute renal failure, including those due to pregnancy and burns
• Excessive fluid retention in the body due to inability to expel fluid associated with signs and symptoms in the kidneys (if diuretic therapy is required)
• Excessive fluid retention in the body due to the inability to expel excess fluid associated with liver disease (if treatment with aldosterone antagonists needs to be supported)
• Hypertension
• Crisis situation caused by high blood pressure (as a supportive measure)
• In cases where it is necessary to strain urine excretion from the body (eg poisoning) as support.

2. What you need to know before you are given UREVER?
DO NOT USE UREVER in the following situations:
If;
• You are allergic to furosemide which is the active substance contained in the drug, or one of the other substances contained in the drug.
• You are allergic to sulfonamide group antibiotics and sulfonylurea group drugs used in the treatment of diabetes
• You have lost too much fluid (through vomiting, diarrhea or excessive sweating)
• You have a disorder that causes an excessive decrease in the volume of your body fluids (including blood).
• You have kidney failure that causes inability to produce urine in the body and this situation does not respond to the use of UREVER
• The potassium level in your blood is extremely decrease.
• The sodium level in your blood is extremely decrease.
• You have a coma-like condition due to a brain dysfunction because of a severe disease in your liver.
• You are breastfeeding your baby.

USE UREVER CAREFULLY in the following cases:
If;
- You have disorders such as bladder emptying that cause partial obstruction in your urine outlet, prostate enlargement, narrowing in the urinary tract (especially in the initial phase of

the treatment with UREVER, your doctor may want to monitor you carefully to ensure urine output).

Your doctor will want to follow you closely regularly in the following situations.

- Low blood pressure
- Diseases where low blood pressure poses a risk: Significant narrowing or blockage in the heart vessels or blood vessels supplying the brain.
- Asymptomatic or obvious diabetes.
- Gout (drop) disease.
- Failure of your kidney function associated with severe liver disease (Hepatorenal syndrome).
- You have a disorder that causes a decrease in the protein level in your blood (for example, a serious kidney disease called nephrotic syndrome may be seen; your doctor will carefully adjust the dose of medication to be used),
- It needs to be used in preterm babies (Your doctor will want to closely monitor kidney functions and perform ultrasonography against the risk of stone formation or calcification foci in the kidneys).

During UREVER treatment, your doctor will want to monitor the levels of electrolytes sodium, potassium and creatinine in your blood. Monitoring is essential if you are at high risk of developing electrolyte imbalances or in case of significant fluid loss due to vomiting, diarrhea or excessive sweating.

Use with risperidone (used in the treatment of some psychiatric illnesses and dementia):
Use of risperidone and UREVER in patients with dementia; It can result in serious side effects such as death. Therefore, your doctor will make the necessary controls in cases where risperidone and UREVER should be used together and will determine your treatment method according to the rate of benefit to be provided by the combined use and the harm it may cause.

If these warnings are valid for you, even at any time in the past, please consult your doctor.

Using UREVER with food and drink
UREVER is used by intravenous or intramuscular injection. Therefore, its interaction with food and drink is not expected.

Pregnancy
Consult your doctor or pharmacist before using this medication.

Unless there are compelling medical reasons, you should not use UREVER during pregnancy. Therefore, pregnancy status should be evaluated before starting treatment.
If you become pregnant during treatment, your doctor may stop the drug and start treatment with a drug from another group or continue the treatment by closely monitoring your baby's development in the uterus.

If you notice that you are pregnant during your treatment, consult your doctor or pharmacist immediately.

Breast-feeding

Consult your doctor or pharmacist before using this medication.

Furosemide passes into breast milk, so you should not use UREVER during breastfeeding. If you need to be treated with UREVER, you should stop breastfeeding to protect the baby from the drug that passes into breast milk.

Driving and using machines

UREVER may cause a significant decrease in blood pressure, difficulty concentrating and impair the ability to react. Therefore, caution should be exercised when using vehicles and machines.

Important information about some of the excipients included in UREVER

This medicinal product contains less than 1 mmol (23 mg) sodium per dose. So essentially it can be regarded as 'sodium free'.

Taking/using other medicines

Medicines not recommended for combined use:

- Chloralhydrate, a sedative and lethargic substance
- Aminoglycosides and other ototoxic drugs (drugs that have a harmful effect on hearing

Medicines need to be precautions when using together

- Cisplatin (used in cancer treatment)
- Lithium (used in the treatment of psychiatric diseases)
- ACE inhibitors or angiotensin II receptor antagonists (used in the treatment of cardiovascular diseases)
- Risperidone (used for the treatment of psychiatric diseases and dementia)

Medicines to be careful when using together

-Nonsteroidal anti-inflammatory drugs (analgesic and anti-inflammatory drugs), including aspirin

- Phenytoin (used in the treatment of epilepsy)
- Corticosteroids, carbenoxolone, licorice root (used in gastrointestinal diseases)
- Digitalis preparations (used in the treatment of cardiovascular diseases)
- Probenecid (used in gout disease)
- Methotrexate (used in cancer treatment)
- Drugs used in the treatment of diabetes
- Epinephrine, norepinephrine (due to its blood pressure increasing properties)
- Curare-type muscle relaxants
- Theophylline (used in the treatment of respiratory diseases) ,
- Some cephalosporins
- Cyclosporine A (Used during organ transplants)
- Contrast agents used to increase the visibility of organs in X-ray examinations.

*If you are currently using any prescription or o*ver-the-counter *medication, or if you have used it recently, please inform your doctor or pharmacist about them.*

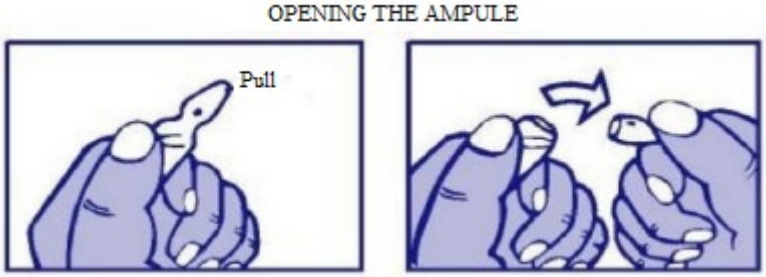
3. How to use UREVER?

Instructions for appropriate use and dose / frequency of administration:

Your doctor will determine the dose of your medicine depending on your illness and apply it to you.

Route of administration and method:

The ampoule form of UREVER is administered only in cases where oral administration is not possible or not effective (eg in intestinal absorption disorder) or if rapid effect is required by intravenous administration. If intravenous therapy is used, it is recommended to switch to oral therapy as soon as possible.



- Hold the ampoule with the dot pointing up.

- If there is any solution in the draw, gently tap or shake the ampoule to make it flow down.

- Holding the ampoule with the dot pointing up, break the pull by pulling it down.

Different age groups:

Use in children:

Your doctor will determine the dose and method of administration of the drug based on your child's age, body weight and disease.

Use in elderly:

In elderly patients and patients with poor general conditions, your doctor will adjust the dose by considering possible deterioration in kidney and liver functions.

Special cases:

Kidney / Liver failure:

Your doctor will determine the dose of your medication based on your illness and the severity of your kidney/liver problems.

Other:

If you have heart failure, severe high blood pressure, your doctor will carefully determine the dose to be used for you, taking into account such situations.

If you have an impression that the effect of UREVER is too strong or weak, consult to your doctor or pharmacist.

If you use more UREVER than you should:

Since UREVER will be used under the supervision of a doctor, necessary measures will be taken to prevent such a situation from developing. In such a situation, an appropriate treatment will be made.

If you use UREVER, more than you should consult to a doctor or pharmacist.

If you forget to use UREVER
Since UREVER will be used under the control of a doctor, necessary measures will be taken to prevent such a situation from developing.

Do not take a double dose to make up for forgotten doses.

Effects that may occur when treatment with UREVER is terminated

If you stop taking UREVER without your doctor's approval, your blood pressure may rise again or excess fluid retention may occur in your body again.

4. Possible side effects?
Like all medicines, there may be side effects in people who are sensitive to the ingredients of UREVER.

If any following situations can be occurred stop using UREVER and IMMEDIATELY inform your doctor or go to the nearest emergency department:

• Itching, hives, other rashes, bullas, usually spontaneous rash on the hands, face and feet that resemble lace, hypersensitivity situation,
• A skin disease that usually progresses with waterfilled blisters-bullas- on the skin on the arms and legs,
• An inflammatory type of skin disease (exfoliative dermatitis) with exfoliation,
• Pinhead-shaped red bruises (purpura), sensitivity to light,
• Spontaneous hypersensitivity reaction,
• Inflammation with blood, swelling and redness on the skin and around the eyes (Stevens Johnson Syndrome),
• A serious disease with fluid-filled blisters on the skin (toxic epidermal necrolysis),
• Blood clot (pain, swelling or tenderness in the legs).

These are very serious side effects. If you have this side effects which one of this, it means that you have a serious allergy to UREVER. You may need emergency medical attention or need hospitalization.

Other reported side effects are listed below. If any of these side effects get serious or if you notice any side effects not listed below in this leaflet, tell your doctor or pharmacist.

Side effects are defined as shown in the following categories:

Very common : It can be seen in at least 1 of 10 patients.

Common : less than one in 10 patients, but more than one in 100 patients.

Uncommon : less than one in 100 patients, but more than one in 1000 patients.

Rare : less than one in 1000 patients, but more than one in 10000 patients.

Very rare : may be seen less than one in 10000 patients.

Unknown : It cannot be estimated from the available data.

Very common

• Changes in the concentrations of chemicals in the blood (electrolyte disturbances)

• Reduction in blood volume (hypovolemia) and dehydration, especially in the elderly.

• Increase in the amount of creatinine in the blood and blood fats called triglycerides

• Low blood pressure (including low blood pressure seen when standing up from sitting or lying position).

Common

• Hemoconcentration (increase in blood concentration due to decreased blood fluid)

• Decrease in sodium, chlorine, potassium values in blood, increase in blood cholesterol and uric acid values,

• Gout attacks (disease characterized by increased uric acid causing inflammation and pain in the joints)

• Hepatic encephalopathy in patients with liver failure (impaired brain function due to liver failure)

• Increase in the amount of urine.

Uncommon

• Decrease in the number of platelets in the blood (unusual bleeding or bruising)

• A decrease in sensitivity to sugar, which should be considered in diabetic patients

• Hearing impairment and sometimes irreversible deafness in patients with an abnormal decrease in the amount of protein in the blood, especially those with severe damage to the kidney

•Nausea

•Itching, rash

Rare

• Decrease in the number of white blood cells (leukopenia)

•An increase in the number of eosinophils (a type of allergy cell) in the blood

•Numbness

• Tinnitus

• Blood vessel inflammation (vasculitis)

• Vomiting, diarrhea

• Kidney inflammation

• Fever

Very rare

• Agranulocytosis (decrease in the number of white blood cells), aplastic anemia (severe decrease in the number of blood cells), a type of anemia (hemolytic anemia)

• Severe abdominal or back pain that may be a sign of acute pancreatitis

• Slow or cessation of bile flow due to an intrahepatic cause, increase in liver enzymes.

Unknown

• Decrease in calcium, magnesium in the blood, increased urea, dry mouth due to metabolic alkalosis, weakness, fatigue, uneasiness, seizures, muscle weakness or cramps, low blood pressure, fast or irregular heartbeat.

• Pseudo-Barter Syndrome in long-term use (manifested by vomiting, inability to urinate and confusion)

• Increased sodium and chloride in urine, inability to urinate.

• Accumulation of calcium salts in the kidneys, renal calculus formation, often causing irreversible kidney damage.

• Increased risk of continuation of "patent ductus arteriosus" (the opening between the two great arteries coming out of the heart, not closing after birth), which is a type of cardiovascular disease, in preterm babies if administered within the first week of life.

• Pain at the injection area.

If you encounter any side effects not mentioned in these instructions for use, inform your doctor or pharmacist.

Reporting of suspected adverse reactions

If you get any side effects not listed in this leaflet, talk to your doctor or pharmacist. You can also report side effects directly to your doctor or pharmacist. You can also report side effects directly to your country's related health authority. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store UREVER?

Keep UREVER out of the sight and reach of children and in its packing.

Store at room temperature between 15-30°C and in its original packaging. Protect from light.

Use in accordance with the expiry date.

Do not use UREVER after the expiration date stated on the packaging.

Do not throw away expired or unused medicines! Give it to the collection system determined by the Ministry of Environment and Urbanization.

Marketing Authorization Holder:
OSEL İlaç Sanayi ve Ticaret A.Ş.
Akbaba Mah. Maraş Cad. No:52
Beykoz/İSTANBUL

Manufacturing Site:
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The patient leaflet was approved on../../….